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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,072	05/10/2005	Andreas Van Eikeren	H01.2-11733-US01	8652
490 7590 03/17/2009 VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER LEWIS, RALPH A	
			ART UNIT 3732	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/517,072	Applicant(s) EIKEREN ET AL.	
	Examiner Ralph A. Lewis	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,3,5-12 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,3,5-12 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 9-12 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dragan (US 5,676,543).

Dragan discloses a method for isolating tooth material comprised of providing an addition reaction silicone (A-silicone)(column 3, line 25), a condensation silicone (C-silicone)(column 3, line 24) and/or polyethers (column 3, line 23) 10 that is mixed from a base portion and a catalyst portion and then “placed about the lower teeth 12, 12’ and gum 14 and allowed to set” (emphasis added - column 3 lines 55-56). After the material 10 is set (cross-links in a self-cure manner) it forms an “impression 20 [that] closely conforms to the shape of the teeth 12, 12’ and gum 14” (emphasis added - column 4, lines 1-3). The material 10 is removed from the patient’s mouth and “filled with a layer of flowable, syringeable or less viscous material 18” (column 4, lines 7-9) which maybe any of the silicone materials used for tray 10 (note column 4, lines 23-24). The flowable material 18 is placed “to flow around the teeth 12, 12’ and gum 14” (emphasis added – column 4, line 30) where it is then allowed to set before removal. Material 18 and its use by Dragan, meet the “covering composition” limitations and it’s

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broadly claimed method of use. The flowable material 18 is not applied to the isolated and exposed tooth material 12 at the right side of Figures 1, 2, 5 and 6 which is capable of being treated with a liquid dental treatment material. It is noted that the present claims specifically call only for a method of isolating tooth material to be treated and not a method of isolating and treating tooth material.

In regard to the limitation that the material is to adhere to the patient's gingival tissue, the examiner is of the position that the Dragan material adheres (at least partially) to a patient's gingival. If applicant's C-silicone is capable of adhering to the gingival, then so is the Dragan C-silicone; the laws of physics apply equally to applicant and the prior art. Applicant discloses, nor claims, any special ingredients in the prior art C-silicone (or A-silicone or polyethers) that make it capable of adhering to soft tissues that other such materials do not typically include.

In response to the present rejection applicant argued that Dragan "does not disclose to apply a composition to the gum around the tooth material to be treated and not onto the tooth material to be treated." The examiner disagrees; Dragan clearly illustrates teeth 12 to the right of Figures 1, 2, 5 and 6 that are left exposed and isolated from the teeth and gum tissue to which the Dragan composition has been applied. The exposed and isolated teeth 12 to the right in Figures 1, 2, 5 and 6 are capable of being treated with a liquid dental treatment means (such as a whitening agent). Applicant argues that the gum tissue immediately below teeth 12 in Dragan Figure 1 are not covered by the composition. The examiner agrees, but applicant only vaguely claims

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covering the gingival “around” the tooth material to be treated. Applicant continues to construe the claims much more narrowly than the broad language of the claims require.

Applicant continues with an argument that the Dragan reference fails to inherently perform the method claimed. The examiner has made no “inherency” argument; it is not asserted that the Dragan method inherently protects the gingiva from a liquid dental treatment means only that the Dragan method is capable of protecting at least a portion of the gingiva around teeth that are capable of being treated with a liquid. The present method claims do not require a liquid dental treatment step and there is no assertion that such a liquid dental treatment step is inherent in the Dragan reference. To the extent that applicant is arguing that the Dragan composition which covers gum tissue is incapable of protecting that gum tissue which it covers from a liquid dental treatment, the examiner simply disagrees. Any substance covering gum tissue would give at least some degree of protection to some vaguely claimed liquid dental treatment.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dragan (US 5,676,543).

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Adjusting the ingredients so that the setting times fall within the ranges claimed would have been obvious to one of ordinary skill in the art as a matter or routine in practicing the Dragan invention.

Claims 2, 3, 5-12 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et al (US 6,305,936) in view of Futami et al, (US 4,778,832) Hare (US 5,661,222), Kamohara et al (US 6,291,546), Zech et al (US 6,677,393), Amstutz et al (US 4,559,013) and Kostner et al (US 4,204,324).

Jensen et al teach the application of a flowable material 28 to the gums of a patient which quickly cross links and isolates the teeth 14 which are to be treated from the gum tissue which is protected behind the applied composition. Jensen et al disclose that the barrier material 28 is a methacrylate composition mixed immediately prior to or during use and applied with a syringe 30 before it cures. While Jensen et al disclose methacrylates, rather than the claimed addition and condensation silicones, Jensen et al do make it clear that other materials having similar properties may be used to accomplish the method (note particularly column 7, lines 9-12).

A-silicones and C-silicones that are mixed in a liquid state prior and then cured by cross linking are well known and commonly used in the dental arts as impression materials for the teeth and gums as evidenced, for example by, Futami et al, Hare, Kamohara et al and Zech et al. It is further known in the art to use such easily shaped silicones to create a thin layer shield over selective teeth and gums as taught by Amstutz et al (column 5, lines 8-15) and Kostner et al (column 3, lines 3-16). To have

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merely substituted common dental A-silicones and C-silicones which are known in the art to make beneficial shields which cover a patient's teeth and/or gums as taught by Amstutz et al and Kostner et al for the methacrylate compositions disclosed by Jensen et al would have been obvious to one of ordinary skill in the art, particularly in view of the Jensen et al disclosure that other compositions are capable of performing the disclosed method.

In response to the present rejection applicant argues that curing of the Jensen et al methacrylate compositions give off more heat during the curing process than A-silicones and C-silicones when curing, that A-silicones and C-silicones are not the specific monomers mentioned by Jensen et al as alternative compositions and that Jensen et al discloses that a photocuring agent may be used. The examiner agrees, Jensen et al do not disclose the claimed composition, otherwise the reference would anticipate the claims. What Jensen et al do teach is applying a flowable composition to a patient's gums which rapidly cures in order to protect those gums from substances (e.g. bleaching agents) used on the teeth. Merely, substituting other known common flowable dental compositions that are readily cured in the method disclosed by Jensen et al for the specific composition used by Jensen et al would have been obvious to one of ordinary skill in the art.

Action Made Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis
March 15, 2009

/Ralph A. Lewis/
Primary Examiner, Art Unit 3732